

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

DRAWINGS ATTACHED

1 203 716

- (21) Application No. 26845/68 (22) Filed 5 June 1968
 (31) Convention Application No. 650 348 (32) Filed 30 June 1967 in
 (33) United States of America (US)
 (45) Complete Specification published 3 Sept. 1970
 (51) International Classification A 61 b 17/18
 (52) Index at acceptance
 A5R 40X6 X4
 (72) Inventor ARNOLD SAMPSON



(54) EXTRA-CORTICAL BONE CLAMP

(71) I, ARNOLD SAMPSON, a citizen of the United States of America, of 220 Meyran Avenue, Pittsburgh, Pennsylvania, United States of America, do hereby declare the invention, for which I pray that a patent may be granted to me, and the method by which it is to be performed, to be particularly described in and by the following statement:—

10 This invention relates to an extra-cortical bone clamp for reducing bone fractures. More particularly, the invention relates to a clamping device specifically adapted to the internal fixation of fractures of long bones, such as the femur, tibia, 15 fibula, radius, ulna, clavicle and ribs, by open reduction.

Internal fixation of long bone fractures has been practiced for many years throughout the world. With the advent of improved non-reactive metals and antibiotics its use inevitably will become more widespread.

Among the various methods and apparatus conventionally used are screw fixation, 25 bone plate and screw fixation, Parham Band fixation, Intra-Medullary pin and nail fixation and compression instrumentation in conjunction with bone plate and screw fixation.

30 None of the previously mentioned methods have been wholly successful, and each has certain inherent drawbacks. With all of the prior art arrangements disclosed, each method can only be used for certain types of anatomic fractures. Screw fixation and Parham Band fixation can only be used for oblique or spiral fractures, but are ineffective for transverse and comminuted fractures. Intra-Medullary pins and nails and 40 bone plates and screws and compression instrumentation devices are effective for transverse fractures, less effective for oblique or spiral fractures and almost useless for severely comminuted or "bag" of bones fractures.

A further objection is noted with the prior art methods disclosed, that because of

the complex nature of these techniques a high degree of surgical skill is required to effectively apply and position these internal 50 fixation devices. In addition, a temporary holding device such as a Loman Clamp must be utilized until the definitive internal fixation device is positioned on the fracture site. Not infrequently, due to improper or 55 inadequate positioning of the definitive fixation device, when the Loman Clamp is removed, the good reduction is lost — and the procedure must be repeated.

A further objection is noted that with 60 most of the prior art methods disclosed, extensive dissection of soft tissue structures and periosteum and wide exposure of the fracture site is necessary. The operation is, therefore, time consuming. These factors 65 enhance the possibility of wound infection, osteomyelitis and non-union of fractures.

In view of the state of the art it would be desirable to provide an internal fixation means which more easily, quickly and 70 effectively positions and maintains fracture site stability, and is effective for many types of fractures.

The extra-cortical bone clamp for reducing bone fractures in accordance with 75 this invention comprises an implant head having a pair of opposed jaws adapted to be moved relatively to each other about a fractured bone, means for locking said pair of jaws in a selected position of adjust- 80 ment, an installation and tensioning tool having a pair of frame members which are adapted to be moved relatively to each other, each of said frame members being removably associated with a different one of 85 said implant head jaws whereby movement of the frame members relatively to each other causes said implant head jaws, when unlocked, to move relatively to each other, and mechanical force transmitting means 90 for causing relative movement of said frame members.

The invention will now be described further with reference to the accompanying

drawings, in which:

Figure 1 is a perspective view showing the implant head and installation and tensioning tool assembled about a fractured tibia;

5 Figure 2 is a perspective view similar to Figure 1, but showing the implant head and installation and tensioning tool in position after tightening of the clamp about the tibia and showing the bone sections in proper anatomical position;

10 Figure 3 is a perspective view similar to Figure 2, but showing the installation and tensioning tool withdrawn from the implant head;

15 Figure 4 is a bottom plan view of the implant head joined to the installation and tensioning tool with the operating knob cut away;

Figure 5 is a vertical sectional view taken along the line 5-5 of Figure 4;

20 Figure 6 is a section taken along lines 6-6 of Figure 5;

Figure 7 is a section taken along lines 7-7 of Figure 5;

25 Figure 8 is a sectional view through lines 8-8 of Figure 5, but showing the implant head separated from the installation and tensioning tool and showing the spring arms in their open position; and

30 Figure 9 is a perspective view of a modified form of implant head.

Reference is now made specifically to the drawings, wherein like reference numerals designate similar parts throughout the several views and wherein the extra-cortical bone clamp assembly constituting the subject matter of this invention is designated generally at 10.

35 The extra-cortical bone clamp comprises two component structures namely, the implant head shown generally at 11 and the installation and tensioning tool 12. The clamp is preferably fabricated in whole or in part from a controlled low carbon content stainless steel such as "Zernalcy" or AISI 316. This material may be cast, precision machined, polished, electro-polished and passivated. It should be understood, however, that any conventional desired material may be used in the construction of the extra-cortical bone clamp.

40 The implant head 11 comprises a frame jaw 13 which, as will become apparent, serves as a stationary portion of the head. This jaw has curved end face as shown at 14 which extends upwardly at a right angle to the base portion of the frame jaw and curves back at its upper extremity. The curved jaw end face is of a width considerably greater than the base portion of the frame jaw, and the end face is provided preferably with a plurality of apertures 15. The inner surface of the curved end face is formed with a plurality of bone engaging projections 16 shown spaced in two rows.

These projections are preferably of pyramidal configuration as shown in Figure 4, although other shapes may be employed. The base of the frame jaw 13 is bifurcated as shown at 17 for a purpose later described. 70 The upper face of each of the legs of the bifurcated portions are serrated at 18 to provide locking ridges. The side faces of the bifurcated portion of the frame jaw are provided with tool locking holes 19 as shown in Figure 3 for cooperation with the locking device on the installation and tensioning tool 12 as hereinafter described in greater detail.

80 The bottom face of the base portion of the bifurcated frame jaw has undercut flanges 20 thereon. These flanges cooperate with a rectangular slide nut 21 as shown in Figure 4.

85 The mating companion portion of the implant head consists of a trolley jaw 22 which in use is adapted to be moved into adjusted position with respect to the frame jaw 13. The trolley jaw includes an integral base or boss 23 having locking serrations 24 on the bottom surface thereof adapted to cooperate with the locking serrations 18 of the frame jaw. The end face 25 of the trolley jaw extends generally vertically, although it is bent inwardly adjacent its 95 top edge and pyramidal projections 26 are provided as shown in Figure 4 for engagement with the bone. A flat boss or horizontal bearing surface 27 is provided at the top of the trolley jaw base 23 and has a drilled recess therein for reception of the locking bolt 28. Tool locking holes 29 are provided on each side of the trolley jaw base for cooperation with locking means provided on the installation and tensioning 105 tool 12 as hereinafter described.

From an examination of Figures 1 through 3, 5, and 6, it will be apparent that when the bolt 28 is loosened within the rectangular slide nut 21, that the trolley 110 jaw may be moved with respect to the frame jaw so that the locking serrations will ride over one another. Once the implant head is in its proper adjusted position such as about the bone portions A, B in Figure 115 1, the bolt 28 may be tightened either by means of a screwdriver or an Allen wrench, so that the frame jaw and the trolley jaw are drawn together through the rectangular slide nut 21 thereby tightly engaging the 120 locking serrations 18 and 24 preventing any further movement of the frame jaw and trolley jaw with respect to each other.

It will be understood that the function of the extra-cortical bone clamp arrangement 125 is to properly tension the implant head about a bone fracture so that the portions A and B are drawn together in proper fixation as shown in Figure 2. Once the proper reduction has taken place, the locking bolt 130

28 may be applied so that further movement of the jaws will be impossible. It will be understood that the implant head is designed to remain in place about the fracture after reduction and may remain about the patient's bone permanently, or if desired, at a later date may be removed during surgery. It will be apparent that the materials used for the implant head must be such as to be totally unaffected by body fluids and tissues even though exposed to the same for prolonged periods of time.

In order to properly install and tension the implant head an installation and tensioning tool 12 is provided. This tool includes an elongated base frame 31 and an elongated trolley frame 32 superimposed thereon and adapted for movement with respect thereto. The base frame 31 is adapted to removably contact the frame jaw of the implant head to restrain movement of the frame jaw and the trolley frame 32 is adapted to be removably connected to the trolley jaw. In this manner, movement of the trolley frame with respect to the base frame will result in movement of the trolley jaw with respect to the frame jaw.

The base frame includes a guides channel 33 as shown in Figures 3 and 4. Formed either integral therewith or as separate members attached thereto are the side frames 34 which extend somewhat forwardly of the base frame. See Figure 8. It should be noted that the distance between the inner faces of the respective side frames is slightly greater than the outer width of the base of the frame jaw 13 to allow the bifurcated frame jaw portions to be received between the side frames 34. Side frame apertures 35 of the same size and shape as the apertures 19 in the frame jaw are provided.

The base frame has upstanding therefrom and formed integral therewith at its rear end an end boss 36. The boss is axially bored and tapped and has a longitudinal opening along its top surface so as to provide a partially threaded bore for reception of an adjusting jack screw as later described. The trolley frame 32 is of generally elongated configuration, although somewhat shorter than the base frame 31 and has formed at its rearward end an upstanding enlargement 37. A vertical bore 38 extends partially through the enlargement and communicates with the end face of the enlargement by means of a horizontal bore 39 forming a narrow keyway 40.

The trolley frame is adapted to be moved fore and aft by means of a jack screw 41 which is threaded for a major portion of its length; the threaded portion being received within the threaded bore of the end boss 36 of the base frame. As

can be seen from a study of Figure 5, the end portion of the jack screw 41 is unthreaded and terminates in a ball fitting 42, having a reduced diameter shaft portion connecting to the unthreaded portion of the jack screw. The ball 42 is adapted to be rotatably received within the vertical bore 38 with the reduced diameter portion received within the narrow keyway 40. A knurled operating knob 43 is secured or integrally formed on the free end of the jack screw for manual operation.

In order to insure proper alignment between the trolley frame and base frame and to achieve accuracy and precision in movement, a guide pin 44 depends from the bottom face of the trolley frame and may be secured thereto by a threaded connection or otherwise as desired. Pin 44 extends into the guide channel 33 of the base frame as can be seen in Figures 4 and 5 and terminates in a rectangular retaining plate 45, the ends of which overlap the bottom of the guide channel 33. The diameter of guide pin 44 is chosen so as to be slightly less than the width of the guide channel 33 and hence serves to maintain proper alignment between the trolley frame and base frame. An integral cross piece 46 extends between the sides of the base frame and serves as a limit stop for forward movement of the trolley frame over the base frame. It will be seen that the guide pin 44 will contact the forward edge of the cross piece 46 thereby limiting movement. In order to insure proper alignment, an auxiliary guide pin 47 depends from the bottom of the trolley frame 32 somewhat rearwardly of the guide pin 44.

In a manner similar to the base frame, the trolley frame is provided with extending side frames 48 each of which are provided with side frame apertures 49.

Actual interconnection between both the trolley frame and base frame with the respective trolley jaw and frame jaw takes place through the intermediary of leaf spring arrangements. A pair of base frame leaf springs are shown at 50 and are attached to the base frame 31 by means of attachment screws 51. These leaf springs extend along the sides of the side frames 34 and are preferably of the same length. Attachment or locking pins 52 are formed integral with or secured on the inner faces of each of the leaf springs 50 adjacent their forward ends and are of such a diameter and length as to be adapted to extend into the base frame side arm apertures 35 and the frame jaw apertures or tool locking holes 19. Movement of the base frame leaf springs 50 with their locking pins is through means of a spring release and compressing bolt 53 extending through the leaf springs and the base

frame. As shown in Figure 7, the fixed end of the spring release and compressing bolt is provided with a hex end 54 adapted to fit within a mating recess in the spring 50 to prevent rotation of the bolt. A knurled cap nut 55 is threaded on the free end of bolt 53. It will be obvious from a study of Figure 8 that tightening of the knurled cap nut 55 will result in compression of the leaf springs 50 thereby moving the locking pins 52 into the apertures 35 in the side frames 34 of the base frame. If the frame jaw 13 of the implant head is in proper position between the bifurcated side frames 34, the pins 52 will extend into the locking holes 19 thereof, thereby securing the frame jaw to the base frame.

The trolley frame is provided with similar locking mechanism. A pair of leaf springs 56, equivalent to the leaf springs 50, are coextensive with the side frames 48, and are attached to the trolley frame by means of attaching screws 57. Securing or locking pins 58 extend inwardly from the outer ends of the trolley frame leaf springs. A spring release and comprising bolt 59 is provided for retraction and controlled extension of the trolley frame leaf springs and is provided with an hexagonal end 60 as shown in Figure 7. A knurled cap nut 61 controls the retraction and extension in a manner similar to the cap nut 55. It will be apparent that the trolley frame may be securely attached to the trolley jaw of the implant head by bringing the trolley jaw base 23 between the extending ends of the trolley frame side frames 48 so that the holes 29 and 49 are in proper alignment. Thereafter, tightening of the cap nut 61 will cause the locking pins 58 to move into the holes thereby securing the trolley jaw to the trolley frame.

The operation of the extra-cortical bone clamp will be apparent by reference to Figures 1 through 3. In Figure 1, the clamp is shown in assembled position with the bolt 28 loosened so that the trolley jaw of the implant head is free to move with respect to the frame jaw 13. The trolley frame and base frame are secured by means of the locking pins passing through the apertures of both the frame jaw and trolley jaw of the implant head. With the jack screw turned all the way out so that the jaws of the implant head are fully extended, the entire clamping arrangement is placed in position about the fracture (Figure 1). It will, of course, be apparent that the amount of periosteum to be stripped will be a minimum and will be limited to the size of the implant head jaws chosen for the particular operation. Once the jaws of the implant head are in proper position, the jack screw 41 will be turned by means of the adjusting knob 43 causing a forward

thrust on the trolley frame thereby moving the trolley jaw toward the end face 14 of the frame jaw. Turning of the operating knob will continue until such time as the bone sections A and B are in proper anatomical position and the fracture has been reduced. This condition is shown clearly in Figure 2.

Once proper positioning of the bone fragments has been achieved by adjustment of the jack screw 41, the locking bolt 28 on the implant head is securely tightened by means of a screwdriver or Allen wrench so that the frame jaw and the trolley jaw of the implant head are secured tightly together through the locking serrations thereon. The cap nuts 55 and 61 on the base frame and trolley frame respectively are then loosened so as to disengage the locking pins 52 and 58 from engagement with the implant head locking holes 19 and 29. Thereafter, the entire installation and tensioning tool 12 may be withdrawn rearwardly as shown in Figure 3. The wound may then be surgically closed and the procedure terminated.

In Figure 9, I have illustrated a modification of the implant head, although it is to be understood that many other forms may be provided based upon specific indications for certain of the bones. The modified implant head of Figure 9 is shown generally at 111 and includes a frame jaw 113 having a curved jaw end face 114. The frame jaw is bifurcated in the same manner as the implant head 11 of the preferred embodiment. In this case, serrations 115 are provided along the entire inner face of the curved jaw end face 114. Locking apertures 119 are formed in the bifurcated sides of the frame jaw. A trolley jaw 122 is provided with serrations 123 along its inner face and is also formed with a locking aperture 124. Operation and function of the modified implant head 111 is similar in all respects to the implant head 11.

Among the post-operative advantages attributed to the present invention are that splinting and casting of the fracture site is usually minimized resulting in less muscle atrophy and joint stiffness, due to early mobilization. Additionally, rapid healing of the fracture is due to the minimal disturbance and stripping of the periosteum. All of these factors contribute to the ease of handling patients both in the hospital, in transport, and during recuperation at home. It is believed that these factors have important implications in the care and rehabilitation of battle casualties in the military services.

WHAT I CLAIM IS:—

1. An extra-cortical bone clamp for reducing bone fractures comprising an im-

- plant head having a pair of opposed jaws adapted to be moved relatively to each other about a fractured bone, means for locking said pair of jaws in a selected position of adjustment, an installation and tensioning tool having a pair of frame members which are adapted to be moved relatively to each other, each of said frame members being removably associated with a different one of said implant head jaws whereby movement of the frame members relatively to each other causes said implant head jaws, when unlocked, to move relatively to each other, and mechanical force transmitting means for causing relative movement of said frame members.
2. A clamp as defined in claim 1, wherein the mechanical force transmitting means comprises a jack screw threadedly received through one of said frame members and having one end thereof in engagement with the other of said frame members.
3. A clamp as defined in Claim 1 or Claim 2, wherein the inner faces of each of said opposed jaws are provided with a plurality of pointed bone engaging projections.
4. A clamp as defined in any preceding Claim, wherein the means to lock said pair of opposed jaws comprises a generally flat surface extending from each of said jaws in superposed relation, locking serrations on said flat surfaces and bolting means adapted to draw said flat surfaces together into locking relationship.
5. A clamp as defined in Claim 4, wherein one of said flat surfaces is bifurcated and said other flat surface has a bore transverse thereto, said bolting means extending through said bore and passing between the opening in the said one flat surface formed by the bifurcation, and a nut threadedly received on the free end of said bolting means.
6. A clamp as defined in any preceding claim, wherein each of the frame members is removably associated with its implant head jaw by means comprising at least one locking hole in each implant head jaw, at least one leaf spring secured at one end to one of said frame members, said leaf springs being normally biased away from said respective frame member, a locking projection on the other end of said leaf springs adapted to be received in locking arrangement within said locking hole of the respective implant head jaw when said leaf spring associated therewith is compressed, and means to selectively compress and release said leaf springs.
7. A clamp as defined in Claim 6, when appendant to Claim 4 or Claim 5, wherein said locking holes are formed in said superposed flat surfaces.
8. An extra-cortical bone clamp for internal fixation of bone fractures comprising in combination, an implant head having a pair of opposed normally relatively movable jaws adapted to be placed about a fractured bone, means to lock said jaws in a selected position of adjustment, locking apertures in each of said jaws, an installation and tensioning tool including a pair of superposed relatively movable frame members, mechanical means for moving one of said frame members relative to the other, a leaf spring extending along each of the sides of each of the frame members, the rearward end of each leaf spring being secured to the respective frame member, said leaf springs being normally biased away from the sides of the frame members but adapted to lie against the sides when compressed, a locking projection on the inner face of each of said leaf springs adjacent the forward end thereof, and means on each frame member to selectively compress and release the leaf springs associated therewith, whereby said locking projections may be brought toward each other by said compressing means to engage in the locking apertures of said jaws to secure the same to the frame members for movement in conjunction therewith.
9. A clamp as defined in Claim 8, wherein the mechanical means for moving one of said frame members relative to the other comprises an upstanding boss on one of said frame members, said boss being axially threaded, and a jack screw threadedly received within said boss and having its forward end connected to the other of said frame members.
10. A clamp as defined in Claim 8 or Claim 9, wherein the means to compress and release the leaf springs on each frame member comprises a bolt extending through said leaf springs and frame member, means restraining said bolt from rotation with respect to said leaf springs and frame member, and a cap nut received on the free end of said bolt and adapted to be screwed down on said bolt thereby drawing said leaf springs against said frame member.
11. A clamp as defined in any one of Claims 8-10, wherein one of said frame members is provided with limit stop means to restrict the amount of movement of one frame member with respect to the other.
12. An extra-cortical bone clamp for reducing bone fractures comprising, an implant head having a pair of opposed jaws adapted to be moved relatively to each other about a fractured bone, means to lock said pair of opposed jaws in a selected position of adjustment, an installation and tensioning tool having a pair of frame members, means removably connecting one of said frame members to one of said im-

- plant head jaws, means on the other of said frame members removably in contact with the other of said implant head jaws to restrain the movement thereof, and
5 mechanical force transmitting means for moving one of said frame members with respect to the other so that the implant head jaw associated therewith will be moved with respect to the other implant head jaw
10 when the jaws are unlocked.
13. An extra-cortical bone clamp sub-

stantially as hereinbefore described with reference to Figures 1-8 or Figure 9 of the accompanying drawings.

TREGEAR, THIEMANN & BLEACH,
Chartered Patent Agents,
Melbourne House,
Aldwych,
London, W.C.2.
Agents for the Applicant.

Printed for Her Majesty's Stationery Office by The Tweeddale Press Ltd., Berwick-upon-Tweed, 1970
Published at the Patent Office, 25 Southampton Buildings, London WC2A 1AY from which copies
may be obtained.

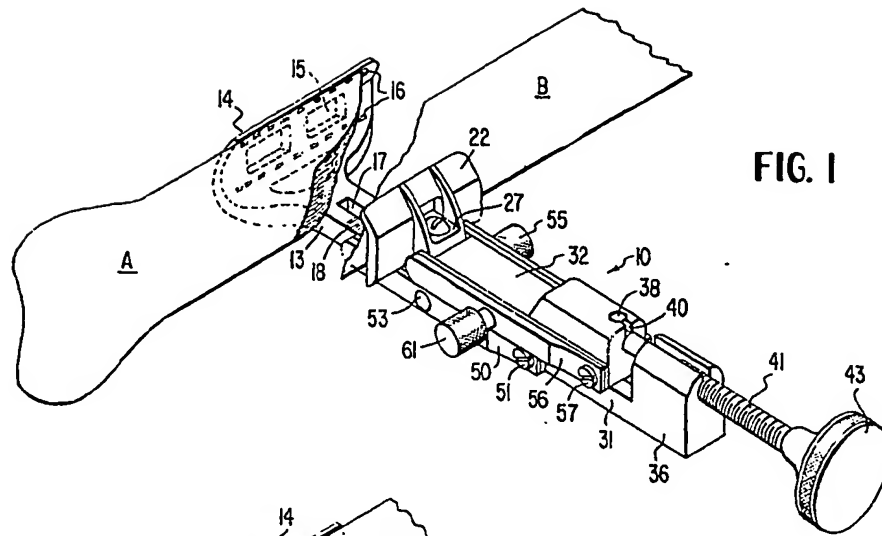


FIG. 1

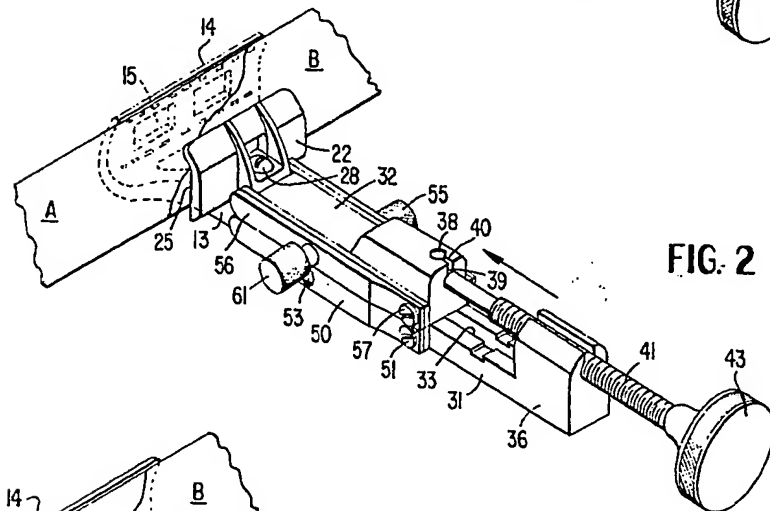


FIG. 2

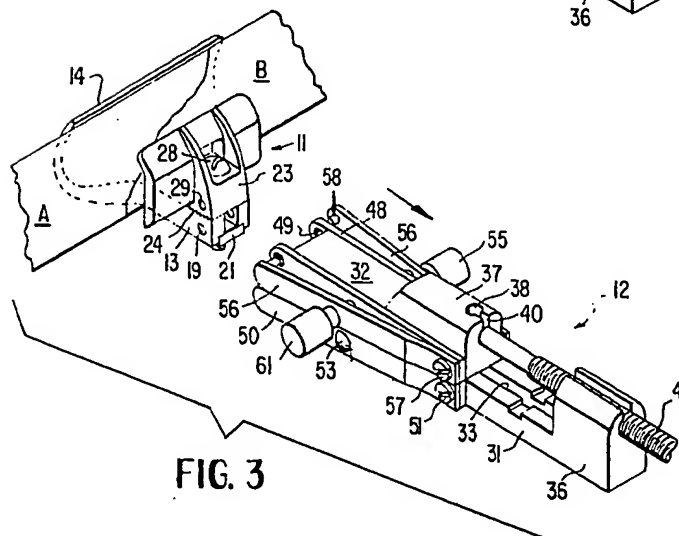


FIG. 3

